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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 09/936,563 | 09/14/2001 | Gerard Mathis | LOM 24 | 7143 |
| 23599 | 7590 | 12/03/2003 | EXAMINER | |
| MILLEN, WHITE, ZELANO & BRANIGAN, P.C. 2200 CLARENDON BLVD. SUITE 1400 ARLINGTON, VA 22201 | | | SIEW, JEFFREY | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1637 | |

DATE MAILED: 12/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/936,563

Applicant(s)

MATHIS ET AL.

Examiner

Jeffrey Siew

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 August 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 and 19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 and 19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 September 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) The newly amended phrase “bond covalently to one member of pair of molecules” is unclear and renders claims 1-17 & 19 indefinite. It is unclear as to whether the phrase refers to the oligonucleotide or not.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6, 8-17 & 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Lehn et al (EP 0321353 June 21/89).

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Lehn et al teach the use of cryptate conjugate oligonucleotides detection assay in which absorption is detected with the fluorescence at 620 nm.(see whole doc. esp. page 20 lines 28-42 experiment D). They teach the addition of various functional groups including halide maleimide or epoxide (see page 40 lines 39-44). They teach that the macropolycyclic compound contains molecular units A,B,C which possess a greater triplet energy than the emission level of the complexed rare earth ion (see page 2) They teach the claimed rare earth cryptates (see pages 2-4 &7). They teach the use of spacer arms with C or C20 alkylene groups (see claim 1).

The limitation of reduced fluorescence quenching of the medium would be inherent to the process by which Lehn et al's teaching increased fluorescence detection of the exact same cryptate conjugates.

In *In re Schreiber*, 128 F.3d 1473, 44 USPQ2d 1429 (Fed. Cir. 1997), the court affirmed a finding that a prior patent to a conical spout used primarily to dispense oil from an oil can inherently performed the functions recited in applicant's claim to a conical container top for dispensing popped popcorn. The examiner had asserted inherency based on the structural similarity between the patented spout and applicant's disclosed top, i.e., both structures had the same general shape. The court stated:

[N]othing in Schreiber's [applicant's] claim suggests that Schreiber's container is of a different shape' than Harz's [patent]. In fact, [] an embodiment according to Harz (Fig. 5) and the embodiment depicted in Fig. 1 of Schreiber's application have the same general shape. For that reason, the examiner was justified in concluding that the opening of a conically shaped top as disclosed by Harz is inherently of a size sufficient to allow [] several kernels of popped popcorn to pass through at the same time' and that the taper of Harz's conically shaped top is inherently of such a shape as to by itself jam up the popped popcorn before the end of the cone and

permit the dispensing of only a few kernels at a shake of a package when the top is mounted to the container.' The examiner therefore correctly found that Harz established a *prima facie* case of anticipation.

In re Schreiber, 128 F.3d at 1478, 44 USPQ2d at 1432.

The instant specification and claims describe the exact cryptate molecules of Lenz et al. Lenz et al teach that the increase fluorescence of the compounds for detection. The reduced quenching would naturally result from the Lenz et al's teaching of his cryptate method steps. The discovery of a new property or result which would be a consequence to the same method steps of the prior does not does not overcome anticipation. The claimed method steps are anticipated by Lenz et al.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lehn et al (EP 0321353 June 21/89) in view of Urdea et al (US 5,124,246 June 23, 1992).

The teachings of Lehn et al are described previously.

Lehn et al do not teach a chain of 5-50 nucleotides.

Urdea et al teach 25mer probes for hybridization. (col. 15. lines 28-42).

One of ordinary skill in the art would have been motivated to apply Urdea et al's teaching of probe lengths to Lehn et al' cryptate conjugates in order to provide adequate probe length for hybridization. Urdea et al state that optimal probe lengths for hybridization range from particularly 25 mers. It would have been *prima facie* obvious to apply the probe lengths to Lehn et al's cryptate conjugate in order hybridize effectively to targets.

4. The response filed 8/29/03 to the 102 and 103 rejections has been fully considered and deemed not persuasive. The response states that the Lehn do not teach that the fluorescent conjugate is bonded covalently to one member of pair of molecules that bind. However, Lehn teach the fluorescent conjugate is bonded to oligonucleotide which is a member of pair of molecules that bind. The rejections are maintained.

SUMMARY


5. No claims allowed.

CONCLUSION

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Siew whose telephone number before January 22, 2003 is (703) 305-3886 and thereafter can be reached at 571-272-0787. The e-mail address is Jeffrey.Siew@uspto.gov. However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route. The examiner is on flex-time schedule and can best be reached on weekdays from 6:30 a.m. to 3 p.m. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703)-308-1119.


JEFFREY SIEW
PRIMARY EXAMINER
11/24/03